

Notice of Allowability

Application No.

10/649,952

Examiner

Bridget E. Bunner

Applicant(s)

MIURA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 09 April 2007.
2. ☒ The allowed claim(s) is/are 19, 20, 26-31, 37-46, and 49 (renumbered as claims 1-19, respectively).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 12/6/06; 7/11/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Alexander Spiegler on 06 June 2007.

The application has been amended as follows:

Cancel claims 16 and 50.

Claim 19 (Currently amended) A method of expanding hematopoietic stem cells and/or hematopoietic progenitors *in vitro* or *ex vivo* comprising administering Cofilin comprising the amino acid sequence of SEQ ID NO: 1 to hematopoietic stem cells and/or hematopoietic progenitors, and expanding said hematopoietic stem cells and/or hematopoietic progenitors *in vitro* or *ex vivo*.

Claim 26 (Currently amended) The method of claim ~~16~~, 19 or 20, wherein the Cofilin is produced by a gene recombinant technique.

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Claim 27 (Currently amended) The method of claim ~~16~~, 19 or 20, wherein the Cofilin includes a sugar chain.

Claim 28 (Currently amended) The method of claim ~~16~~, 19 or 20, wherein said method further comprises administering a cytokine.

Claim 37 (Currently amended) The method of claim ~~16~~, 19 or 20, wherein the Cofilin is encoded by SEQ ID NO: 2.

Claim 39 (Currently amended) A method of promoting differentiation of hematopoietic stem cells and/or ~~[[,]]~~ hematopoietic progenitors, ~~or a combination thereof~~ in vitro or ex vivo, said method comprising administering Cofilin comprising the amino acid sequence of SEQ ID NO: 1 and a cytokine to hematopoietic stem cells and/or hematopoietic progenitors, and promoting differentiation of hematopoietic stem cells and/or ~~[[,]]~~ hematopoietic progenitors, ~~or a combination thereof~~ in vitro or ex vivo.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

The specification of the instant application teaches that isolated mouse bone marrow cells are incubated in culture with the human non-muscle type Cofilin protein of SEQ ID NO: 1 and that at 6 and 10 days, the number of HPP-CFC colonies in the recombinant human nonmuscle-type Cofilin groups at concentrations of 2500 ng/ml, 250 ng/ml are significantly increased compared to control (page 33, [107-108; Figure 4]). Additionally, the specification discloses that the human nonmuscle-type Cofilin in combination with SCF and FL caused cultured human umbilical cord blood derived CD34 positive cells to expand significantly as compared to control

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(pg 36, [116]; Figure 6A). Human nonmuscle-type Cofilin in combination with SCF and FL also caused an increase in the colony formation of CFU-GM (colony-forming unit granulocyte, macrophage), BFU-E (burst-forming unit erythroid), and CFU-Mix (colony-forming unit, mixed) as compared to controls (pg 36-37; Figure 6B-6D).

The Cofilin protein of SEQ ID NO: 1 of the instant application is well-known in the prior art and is a member of actin-binding proteins (ABP) that bind to actin filaments (F-actin) at a molar ratio of 1:1 in response to a variety of signals, thus regulating the physical conditions of actin and performing the primary function in the reconstitution of the actin-based cytoskeleton (page 3, paragraph [10]; see also for example, Vartiainen et al. Mol Cell Biol 13: 183-194, 2002; Maciver et al. Genome Biol 3:1-12, 2002; both previously made of record). However, the prior art does not disclose Cofilin participating in the growth or differentiation of hematopoietic stem cells and/or hematopoietic progenitors.

Thus, the instant application discloses the unexpected finding that the Cofilin protein of SEQ ID NO: 1 stimulates the growth and differentiation of hematopoietic stem and/or hematopoietic progenitor cells.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

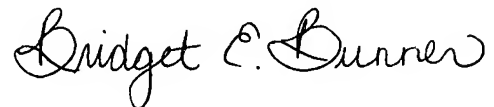
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
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08 June 2007



**BRIDGET BUNNER
PATENT EXAMINER**